EXHIBIT R

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May 30, 2018

Via E-mail and Overnight Mail

The Honorable Alex M. Azar II
Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Email: secretary@hhs.gov

Re: OPTN Liver Distribution and Allocation Policy

Dear Secretary Azar:

This firm represents several individuals who are currently awaiting liver transplants in the metro New York area. The issues raised in this letter are of utmost urgency and are literally a matter of life and death. We request that you give this letter your immediate attention so that you can either grant our request or we can seek immediate judicial relief.

Our clients are currently on the liver transplant waiting list and registered with transplant centers in the New York area. They have a variety of different MELD (Model for End-Stage Liver Disease) scores but are all disadvantaged by the arbitrary geographic criteria used in current OPTN policy as well as in the new liver distribution and allocation policies approved by the OPTN Board in 2017. Our clients do not seek special treatment. They simply seek to be treated fairly and consistent with the law. We respectfully request that you exercise your authority to set aside an antiquated and inflexible policy established by a federally-created organization supervised by your Department, so that all citizens can be considered for available livers based on medical priority without regard for arbitrary geographical boundaries.

We believe the Secretary is best positioned to effect the necessary change. Notwithstanding, given our clients' medical conditions, absent meaningful change and compliance with the law we are prepared to seek judicial intervention should that be necessary. See Holman v. United States Department of Health and Human Services, (S.D.N.Y. 17-CV-09041).

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Request

We request that you take immediate action and direct the Organ Procurement and Transportation Network (OPTN) to set aside those portions of OPTN Policy 9 that require livers from deceased donors to be allocated to candidates based on arbitrary geographic boundaries instead of medical priority. Specifically, Table 9-6 currently requires livers to be allocated based on arbitrary geographic boundaries, namely, the Organ Procurement Organization's (OPO) region or OPO's donor service area (DSA). We request that you direct the OPTN to immediately revise the distribution of livers to follow a zone based distribution consistent with both the law and how other organs (*e.g.*, lungs and hearts) are distributed.

Current OPTN Liver Policy Does Not Comply With the Law

The law, as codified in the Code of Federal Regulations, is clear: "OPTN allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on the candidate's place of residence or place of listing except to the extent needed to satisfy other regulatory requirements." OPTN/UNOS Briefing Paper at p.1.[1]

It is equally clear that OPTN liver policy has for the last two decades violated the law. Specifically, the OPTN had determined that "current regional boundaries often physically separate urgent candidates from donors in close proximity. The result is that in some areas of the United States, candidates must reach a higher MELD or PELD score in order to get a transplant."[2] Id. The unfairness of the current system was underscored in the OPTN/SRTR's 2016 Annual Data Report: Liver which found "there is wide geographic variability in the degree of sickness, based on median MELD scores, in candidates for deceased donor transplants []. The highest reported median MELD score was 39, in Los Angeles, California (CAOP), and the lowest 20 in Indianapolis, Indiana (INOP)."[3] New York has some of the nation's highest average median MELD score at transplantation.

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[1] https://optn.transplant.hrsa.gov/media/2222/liver_pcproposal_201707.pdf

[2] The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee identified variance in median MELD score as having "been shown to accurately reflect (with few exceptions) a candidate's severity of illness." Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation at p. 9 (2014) (https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf).

[3] OPTN/SRTR 2016 Annual Data Report: Liver (first published January 2, 2018).

Over the last two decades, the OPTN has worked to develop policies that would put its liver distribution and allocation policy in compliance with the law. To date it has failed to so. Part of the reason for this failure is the OPTN's continued adherence to OPO and DSA boundaries as part of its liver distribution and allocation policy. There is no legal or medical basis for these arbitrary boundaries to have any role in liver allocation. As recognized by the OPTN, "[w]hile the regions provide an effective mechanism for participation in the OPTN, neither the regional boundaries nor the DSA boundaries were designed to optimally distribute organs." *Id.* at p.2. Moreover, in the context of other organs, the OPTN Executive Committee has recognized that "DSAs might not be the best proxy for geography, as DSAs have disparate sizes, shapes, and populations. DSAs as drawn today do not appropriately address those concerns in a way that is rationally determined, consistently applied, and equal for all candidates."[4] OPTN/UNOS Mini Brief at p. 2.

The New OPTN Liver Policy Will Not Comply With the Law

Following OPTN Board approval, in December 2017, OPTN/UNOS published a new Policy Notice, Enhancing Liver Distribution. The new policy recognizes that "[r]egional and donation service area (DSA) boundaries determine current liver distribution," which improperly limits access to livers based on arbitrary geographic criteria. However, instead of doing away with these improper criteria, the new policy introduces a "150-nautical mile radius proximity circle around the donor hospital" in addition to the existing and improper DSA-based boundaries. While this "proximity circle" is a step in the right direction, it does not put the new policy in compliance with the law nor does it meaningfully help reduce disparity in liver allocation. The DSA and regional boundaries are entirely arbitrary and adding a 150 mile proximity circle without removing the arbitrary boundaries has no medical or legal basis.

Plainly stated, OPTN liver distribution policy will not comply with the law so long as it continues to adhere to arbitrary regional or DSA criteria. There is no medical or legal basis for these random boundaries and patching a fundamentally flawed system will not work.

In June 2017, the OPTN Board also approved a new National Liver Review Board (NLRB) "to provide fair, equitable, and prompt peer review of exception candidates."[5]

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[4] https://optn.transplant.hrsa.gov/media/2314/broader_sharing_lungs_20171124.pdf

[5] OPTN/UNOS Briefing Paper Proposal to Establish a National Liver Review Board at p. 3. (https://optn.transplant.hrsa.gov/media/2176/liver_boardreport_nlrb_201706.pdf)

The NLRB is intended to change the way MELD exception points are determined and assigned. The NLRB is expected to assign exception points to candidates at a fixed value just below the median MELD at transplant for adult recipients within the DSA. Id. While there are many valid aspects to the NLRB, the continued use of DSA-based allocations, as manifested by setting exception points to just below the median MELD in the DSA, is entirely arbitrary and inconsistent with the law.

It is Time to Change OPTN Liver Policy

Over the last two decades much discussion has been had and many studies have been conducted but the OPTN has still been unable to implement a system for livers that complies with the legislative mandate that organ allocation be based on medical – not geographic – priority. The OPTN has had nearly twenty years to study and fix the liver distribution system on its own. It is now time for the Secretary to exercise his authority and take charge.

Action by the Secretary is not unprecedented and is necessary to implement meaningful change. On November 21, 2017, the Acting Secretary directed OPTN to conduct an emergency review of the use of DSAs in the OPTN lung distribution policy. The OPTN/UNOS Executive Committee convened the following day and by November 24, 2017 (three days later and over Thanksgiving) a new OPTN lung distribution policy was revised and implemented.[6] The new policy did away with regional and DSA distribution criteria. There is no legitimate reason why the Secretary and OPTN should not take similar action with regard to liver policy.

We recognize the unfortunate reality that liver transplants are a significant source of revenue for transplant centers, particularly in those areas of the country where there is a surplus of donated livers.[7] As one commentator noted, the opponents to change (and compliance with the law) "are affiliated with transplant programs in regions with less

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[6] In a matter of hours, OPTN and UNOS were able to implement a new lung policy, including reprogramming the UNet system. In contrast, the new liver policy passed in December 2017 will require thousands of hours of extensive computer programming and testing, which will delay implementation by up to year. This level of complication is the result of a patchwork system of fixes to a fundamentally flawed allocation policy.

[7] A 2017 Milliman report estimates that the average liver transplant results in total billed charges of $812,500. 2017 U.S. Organ and Tissue Transplant Cost Estimates and Discussion, Milliman Research Report, August 2017 (http://www.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf)

liver scarcity" and are motivated "by the desire to protect the strong financial position afforded to transplant programs in areas with lower liver scarcity, and the more admirable desire to protect one's own patients who would be forced to wait longer for a liver."[8] Decades ago, Congress made clear that organs are a national resource and neither financial gain nor the protections of one's own patients or transplant program is an appropriate or legally supportable basis for organ distribution.[9]

Authority

The Secretary has the authority to direct OPTN to take action under 42 C.F.R. 121.4(d)(2) and (3). Those provisions provide the Secretary with authority to "[d]irect the OPTN to revise the policies or practices consistent with the Secretary's response to the comments" or "[t]ake such other action as the Secretary determines appropriate." The Secretary also has authority to vary OPTN policies on a limited basis under 42 C.F.R. 121.8(g).

Background

A. OPTN and UNOS

The National Organ Transplant Act of 1984 (NOTA) created the OPTN. The current version of NOTA is codified at 42 U.S.C. § 274, which provides that the Secretary must establish and operate the OPTN in accordance with the requirements of NOTA.

NOTA empowers the Secretary of the Department of Health and Human Services (HHS) to contract with UNOS, a non-profit private organization, to operate the OPTN. The Secretary contracts with UNOS through the Health Resources and Services Administration (HRSA). The Secretary has also promulgated regulations that govern the OPTN (42 C.F.R § 121). These regulations provide, among other things, that OPTN's Board of Directors shall be responsible for developing policies for the operation of the

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[8] Brendan Parent, Arthur L. Caplan, *Fair is fair: We must re-allocate livers for transplant,* BMC Med Ethics. 2017; 18: 26.

[9] "This objective reflects the views of many commenters on the proposed regulations, as well as the finding of the American Medical Association in its Code of Medical Ethics: 'Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.'" Final Rule at p. 16297.

OPTN, including "[p]olicies for the equitable allocation of cadaveric organs in accordance with §121.8." 42 C.F.R. §121.4(a)(1).

Section 121.8(a) provides as follows:

(a) ***Policy development.*** The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

42 C.F.R. §121.8(a) (emphasis added).

NOTA and regulations promulgated thereunder clearly require that OPTN policies for organ distribution and allocation be equitable, that they provide for organ

distribution based on medical severity, and that they *not* base organ distribution on a candidate's place of residence or listing. My clients do not seek special treatment. They only ask for the equitable treatment that they are entitled to under the law.

B. OPTN's Liver Distribution and Allocation Policy Unfairly Allocates Livers Based on Geography

The OPTN rules for distribution and allocation of livers are set forth in OPTN Policy 9.

Policy 9.6.E. (Allocation of Livers from Deceased Donors at Least 18 Years Old) provides that "[l]ivers from deceased donors at least 18 years old are allocated to candidates according to *Table 9-6* below." Table 9.6 (Allocation of Livers from Deceased Donors at Least 18 Years Old) sets forth 52 classifications of distribution and allocation priority. Unlike other organs that allocate among candidates based on medical priority and non-arbitrary geographic limitations, the liver allocation system includes arbitrary geographic limitations based on OPO region or OPO DSA.

Under the current system, if a liver is accepted for a candidate listed with a MELD score within the local DSA, it is not offered to a candidate in the broader reach of the organ even if that non-local DSA candidate has a greater medical need, *i.e.*, a higher MELD. Moreover, because of the arbitrary boundaries of DSAs, an available liver may not even be offered to the candidate closest to the donor hospital even if that candidate has a higher MELD score. Instead of following such a patently illogical distribution priority rule, organs should be made available to a candidate based on a logistically reasonable radius to the transplant hospital. Although livers have a preservation of time that is 200% of hearts and lungs – up to 12 hours or longer – livers are still distributed based on arbitrary local boundaries, while other organs have transitioned to a non-arbitrary prioritization.

Simply put, OPTN Policy 9 is arbitrary and violates the legislatively mandated requirement that organ allocation be "based on sound medical judgment" and "not be based on the candidate's place of residence or place of listing." 42 C.F.R. §121.8(a).

The new policy approved by the OPTN Board in December 2017, does not solve this problem. As set forth below, the new policy implements an allocation hierarchy that still includes region and DSA criteria. Without eliminating these improper criteria implementing a zone based system (like other organs) the liver distribution policy will continue to prejudice thousands of people on the waitlist and violate the Final Rule.

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Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Adult or pediatric status 1A
2	Region or Circle	Pediatric status 1B
3	Region or Circle	Any of the following: •At least 18 years old at time of registration and calculated MELD of at least 32 including proximity points •At least 18 years old at time of registration and has an approved HAT exception •Less than 18 years old at time of registration and allocation MELD or PELD of at least 32 including proximity points
4	DSA	MELD or PELD of at least 15
5	Region or Circle	MELD or PELD of at least 15

Similarly, the new NLRB policy approved by the OPTN Board in June 2018 also improperly relies on arbitrary DSA criteria.

Generally, a waitlist candidate's MELD score is intended to reflect the candidate's disease severity and his or her risk of mortality without access to liver transplant. In some instances, *e.g.*, liver cancer, a candidate receives an "exception" MELD score if the urgency of their need for liver transplant is not reflected by the calculated or "lab-based" MELD score. The new policy provides a default standard exception of the lesser of: (i) 34; or (ii) three points below the median MELD at transplant (MMaT) score by DSA. By linking the number of exception points to a fixed value three points below the median MELD within the DSA, the policy improperly includes arbitrary geographical boundaries in the liver allocation scheme.

C. OPTN's Policy 9 Is Recognized by OPTN and the Medical Community as Being Arbitrary

For years, the medical community has recognized the requirement that livers be allocated within the local OPO or DSA before being offered more broadly is dangerously flawed. Multiple medical studies support the need for a change to the current policies that allocate livers based on arbitrary geographical boundaries. Gentry SE, Massie AB, Cheek SW, Lentine KL, Chow EH, Wickliffe CE, Dzebashvili N, Salvalaggio PR, Schnitzler MA, Axelrod DA, Segev DL, *Addressing geographic disparities in liver transplantation through redistricting*, American Journal of Transplantation, 2013; 13:2052-2058; Yeh H, Smoot E, Shoenfeld DA, Markmann JF, *Geographic inequity in access to livers for transplantation*, Transplantation 2011; 91: 479-486; Schwartz A,

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Schiano T, Kim-Schluger L, Florman S, *Geographic disparity: the dilemma of lower socioeconomic status, multiple listing, and death on the liver transplant waiting list*, Clinical Transplantation 2014; 28: 1075-1079; Axelrod DA, Vagefi PA, Roberts JP, *The evolution of organ allocation for liver transplantation: tackling geographic disparity through broader sharing*, Annals of Surgery August 2015; Vol. 262, No. 2, 224-227.

Conclusion

HHS, OPTN, and my clients all have a common goal – to make livers available to those who need them the most based on medical criteria. All we request is that this goal be appropriately reflected in OPTN Policy 9 and that it be done in a timely manner so that it is not too late for my clients. We are not asking for anything more than what is provided in the law. Discretion and power rests with the Secretary to direct the OPTN for exactly this purpose – to avoid inequity and injustice. We ask that you set aside these flaws in OPTN Policy 9 until the OPTN can devise a better system after proper notice and comment to the public. The history of the OPTN's liver policy efforts shows that without intervention by the Secretary (or the judiciary, as may be necessary) the OPTN may not be able to make the necessary changes in time for liver candidates like my clients and many others.

I hope that you will exercise your discretion in this matter as requested.

Yours truly,

Motty Shulman

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